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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/930,312	08/15/2001	Peter Lind	PHRM-0366	3604

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EXAMINER

JIANG, DONG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 07/17/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/930,312

Applicant(s)

LIND, PETER

Examiner

Dong Jiang

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-79 is/are pending in the application.
- 4a) Of the above claim(s) 23, 24, 30-66 and 73-79 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22, 25-29 and 67-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-79 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 & 7-10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED OFFICE ACTION

Applicant's election of Group I invention, claims 1-22, 25-29 and 67-72, in Paper No. 13, filed on 12 May 2003 is acknowledged. Additionally, applicants indicate that no serious burden would be imposed upon the Examiner by combining several of the groups. This is not found persuasive for the reasons set forth in the last Office Action, paper No. 11, and for the reason below. Consistent with current patent practice, a serious burden may be established by (A) separate classification thereof; (B) a separate status in the art when they are classifiable together; or (C) a different field of search. In the instant case, Groups I-XV are patentably distinct inventions as shown by their separate classification, indicating each distinct subject has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. As stated in the MPEP 803, "a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP 802.02.". Further, a search is directed not only to art, which would be anticipatory, but also to art that would render the invention obvious. Thus, the groups require divergent searches, and to search all groups of inventions would constitute serious burden.

The requirement is still deemed proper and is therefore made FINAL.

Currently, claims 1-79 are pending, and claims 1-22, 25-29 and 67-72 are under consideration. Accordingly, claims 23, 24, 30-66 and 73-79, as non-elected inventions, are withdrawn from consideration.

The references listed on the PTO-1449 in paper No. 4 are not present in the current application file. In response to this Office Action only, applicants may submit another set of the same references, and the Examiner will consider them as though they were submitted with IDS in paper No. 4. Note: US patents have been considered.

It is also noted that the relevance of references FX in IDS paper No. 7, and 160 and 162 in IDS paper No. 10 cannot be assessed as these references are nucleic acid sequences, and no indication of relevance or alignment to the disclosed sequences has been provided.

Formal Matters:

Priority

This application claims priority to US provisional applications 60/225,262. For the following reasons, the Examiner finds that the present claims 1-22, 25-29 and 67-72 are not supported in the manner required by 35 U.S.C. 101 and 112, first paragraph by the prior application, thus none of present claims is entitled to the benefit of the filing date of the prior application.

The priority applications merely discloses the polypeptide sequence of SEQ ID NO:2 and the polynucleotide of SEQ ID NO:1 encoding said polypeptide. The prior applications fails to provide any specific, substantial and credible utility, and provides no guidance or working examples to teach how to used the claimed invention. Therefore, the Examiner is not able to establish that the priority document satisfies the utility/enablement requirement of 35 U.S.C. 101/112, first paragraph. As such, the claims of the instant application are not entitled to the benefit of the filing date of prior application listed above.

Title

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are directed.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the Examiner is unable to find the basis in the specification for the limitation in claim 72 that “a host cell according to claim 71 that has been *co-transfected* with a polypeptide ...”.

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Claims

Claim 67 is objected to as being dependent upon a non-elected claim. The applicant is required to rewrite the claim in independent form including all of the limitations of the base claim and any intervening claims.

Objections and Rejections under 35 U.S.C. §101 and §112:

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-22, 25-29 and 67-72 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by a credible, substantial, and specific, or a well-established utility.

Claims 1-22, 25-29 and 67-72 are directed to an isolated nucleic acid molecule of SEQ ID NO:1 or a nucleic acid molecule encoding a polypeptide having SEQ ID NO:2, variants and fragments thereof, a vector and a host cell thereof, and a method of recombinant expression of such. Said polypeptide is a putative G protein-coupled receptor (GPCR), and designated nGPCR-1079.

The specification discloses a nucleic acid of SEQ ID NO:1 encoding a polypeptide having SEQ ID NO:2, which has 107 amino acids. Based on its sequence homology to other known GPCRs (Example 1), the specification asserts that SEQ ID NO:1 encodes a GPCR, that the polynucleotide and polypeptide of the invention are useful in diagnostic assays, such as screening or detecting mutations (page 42, [000164]; page 54, [000209]; and page 57, [000216]), treatment of diseases and gene therapy (page 42, [000166] – [000166]; page 50, [000190]; page 51, [000193]; and page 52, [000200]), drug discovery (page 45, [000174]).

The asserted utilities are not considered to be specific, or substantial because the specification fails to provide specific support for these uses, nor any information about the ligand, a particular function, or biological significance of the polypeptide encoded by the nucleic acid. The speculation that the disclosed protein would have potential functions as other known GPCRs because they are putative G protein-coupled receptors, and share amino acid sequence similarity of GPRs cannot be accepted in the absence of supporting evidence, because it is well

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known that hundreds and thousands of proteins belong to GPCR family, yet have extremely diverse, and sometimes even opposite biological activities and functions. For instance, dopamine receptor D1 couples to Gs, and stimulates intracellular cAMP production upon binding to an agonist, whereas dopamine receptor D2 couples to Gi, and inhibits intracellular cAMP production upon binding to the same agonist, and both receptors belong to the same GPR family. Additionally, Skolnick et al. (Trends in Biotechnology, 2000) teaches that because proteins can have similar structures but different functions, determining the structure of a protein may not necessarily reveal its function (see entire article, especially Box 2). While the sequence homology may suggest that nGPCR-1079 polypeptide is a member of GPCR family, however, it by itself does not suggest any specific or substantial utility for the reasons above.

Therefore, each of the disclosed utilities requires additional knowledge about the claimed nucleic acids and proteins encoded thereby before the nucleic acid or proteins can be used for a specific purpose, such as those set forth in the specification. The specification does not provide any such specific information about SEQ ID NO:1 and 2. The disclosed uses in diagnosis, treatment, and drug development are not specific nor substantial in the absence of knowledge of the ligands which said nGPCR-1079 binds, or any disclosed gene mutation, or any disease or condition which could be so diagnosed, or treated. Therefore, there is no immediately evident patentable use for the claimed nGPCR-1079 polypeptide or the nucleic acid encoding such. Upon further research, a specific, and substantial utility might be found for the claimed isolated nucleic acid and protein. This further characterization, however, is part of the act of invention, and until it has been undertaken, the claimed invention is incomplete.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-22, 25-29 and 67-72 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial or credible utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Further, *even if* the specification taught how to use the nucleic acid encoding the human nGPCR-1079 polypeptide, enablement would not be commensurate in scope with claim 1 and the dependent claims 3, 5-22, 25-29, and claims 67 and 68, which encompass *homologous variants* of SEQ ID NO:1 or a nucleotide encoding SEQ ID NO:2 or homologs thereof (claims 1, 3 and 27, for example), *fragments* of same (claim 22, for example), and *allelic variants* (claim 67, for example).

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with the claims. The specification discloses merely *one* polynucleotide having SEQ ID NO:1, which encodes a human nGPCR-1079 polypeptide with SEQ ID NO:2. No variant or fragment of any kind meeting the limitations of these claims were ever identified or particularly described. The specification provides neither guidance, nor working example to teach how to make any of variants or fragments of nGPCR-1079 polypeptide as no structural-functional relationship is disclosed. Since no biological function of nGPCR-1079 polypeptide is disclosed in the specification, and since one skilled in the art could not determine with a reasonable expectation of success what a biological function of nGPCR-1079 polypeptide would be, the skilled artisan would not be able to make nGPCR-1079 polypeptide variants or fragments, and test them for a biological activity, because one is not disclosed. Therefore, it would require undue experimentation to practice this invention as claimed, because the skilled artisan would have no reasonable expectation of being able to use the nGPCR-1079 polypeptide variants or fragments for any purpose stated in the specification. Further, as the biological property of nGPCR-1079 polypeptide is unknown, the specification has not taught a skilled artisan how to distinguish the hybridization variants, which may have distinct functional properties from nGPCR-1079 polypeptide, and how to use them. Additionally, the skilled artisan would not know how to use the small fragments which neither is specific to nGPCR-1079, nor encodes a biological active portion.

Claims 1-4, 8, 22, 27, 67, 69, 71 and 72 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a

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way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 3, 22, 27, 67, 69 are drawn to various variants of SEQ ID NO:1 and nucleic acids encoding SEQ ID NO:2 or homologs thereof (homologous, allelic, and hybridization variants, as set forth above), and fragments. The specification discloses one nucleic acid of SEQ ID NO:1 encoding nGPCR-1079 of SEQ ID NO:2. No other variants of SEQ ID NO:1, or nucleic acids encoding SEQ ID NO:2 meeting the limitations of these claims were ever identified or particularly described.

Additionally, claims 1-4, 8, 22, 27, 67, 69, 71 and 72 recite SEQ ID NO:1 or 2, or nGPCR-1079, which are defined by the specification as a GPCR or the nucleic acid encoding thereof. The prior art has established that GPCRs share a common structural feature as they have seven transmembrane domains and six intra- and extra-cellular domains. However, the present SEQ ID NO:2 has merely 107 amino acid residues, which are far less than the number of residues required to constitute a GPCR. Obviously, the present SEQ ID NO:2 is not a complete sequence of a GPCR.

The skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated nucleic acid of SEQ ID NO:1 or encoding the amino acid sequence of SEQ ID NO:2, but not the full breadth of the claims meets the written description provision of 35 U.S.C. §112, first paragraph. This is particularly important in absence of a

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specific known activity. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).]

Claims 1-22, 25-29 and 67-72 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Claims 1-4, 8, 22, 27, 67, 69, 71 and 72 recite SEQ ID NO:1 or 2, or nGPCR-1079, which are defined by the specification as a GPCR or the nucleic acid encoding thereof. For the reasons addressed above, the present SEQ ID NO:2 is not a complete sequence of a GPCR. The specification does not provide any guidance or working example demonstrating the nGPCR-1079 of SEQ ID NO:2 is functional. It is known in the art that the biological function of a GPCR depends upon the entirety of most of the domains of the molecule. For example, Javitch et al. (Proc. Natl. Acad. Sci. USA, 1994, 91: 10355-10359) teaches that the binding site in most GPCRs is formed among their membrane-spanning segments (page 10355, the third paragraph of the right column). Probst et al. (DNA and Cell Biol., 1992, 11(1): 1-20) teaches that the shortest sequence of a GPCR has 324 amino acids, and the longest one has 744 amino acids (page 2, the left column). As such, it is unlikely that the present nGPCR-1079 of SEQ ID NO:2, which has merely 1/3 of the minimum length of a GPCR, is a functional GPCR even though it may be a portion of a GPCR, and undue experimentation is required prior to using the present invention for any purpose as claimed.

Due to the large quantity of experimentation necessary to determine whether the present nGPCR-1079 of SEQ ID NO:2 has any functional activity, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same,

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the complex nature of the invention, the state of the prior art establishing that the biological activity of a GPCR depends upon the entirety of most of the domains of the molecule undue experimentation would be required of the skilled artisan to make and/or use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-22, 25-29 and 72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because it is not clear what "homologous" is meant to indicate. At page 8 of the specification, it is stated that the phrase "homologous nucleotide sequence", or "homologous amino acid sequence", ... refers to sequences characterized by a homology, at the nucleotide level or amino acid level, of at least the specified percentage ([00038]). However, the claim does not specify the percentage of the sequence identity or any other objective measurement. The metes and bounds of the claim, therefore, cannot be determined. Claims 3 and 27 are similarly indefinite.

Claim 10 is indefinite for the recitation of "said vector is a viral particle" as a vector is not the same as a viral particle. A viral particle indicates the entire entity of a virus, and may contain a vector. "Said vector is a viral vector" is suggested. Claim 11 is similarly indefinite.

Claim 22 is indefinite because it is unclear whether said 10 nucleotides is the same as a nucleotide sequence complementary to at least a portion of SEQ ID NO:1.

Claims 25 and 26 are indefinite for the recitation of "an *acceptable* carrier or diluent" because it is unclear for what it is acceptable.

Claim 27 is further indefinite for using inclusive language "and" in "a polypeptide that comprises a sequence of SEQ ID NO:2 *and* homologs thereof", which reads on that the polypeptide comprises *both* SEQ ID NO:2 and homologs thereof. The alternative term "or" is suggested.

The remaining claims are rejected for depending from an indefinite claim.

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Rejections Over Prior Art:

The following rejections under 35 U.S.C. § 102 and 103 are made in view of the determination that the effective filing date for the instantly claimed invention is 8/15/01, which is the actual filing date of the instant application.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-22, 25-29 and 67-71 are rejected under 35 U.S.C. 102(e) as being anticipated by Paszty et al., US 2002/0123618.

Paszty discloses a nucleic acid, SEQ ID NO:1, which comprises the sequence of SEQ ID NO:1 of the present invention with 100% sequence identity (see appended computer printout of sequence search result), and encodes a human GPCR designated LGR8, and having an amino acid sequence of SEQ ID NO:2. Paszty's LGR8 of SEQ ID NO:2 comprises the sequence of SEQ ID NO:2 of the present invention with 100% sequence identity (see appended computer printout of sequence search result). Additionally, Paszty teaches an allelic variant of SEQ ID NO:1 (claim 2, part (b)). Further, Paszty teaches an expression vector including a plasmid, or a viral vector such as pFastBacDual and others (page 17, [0193], and page 29, [0323]), wherein the vector comprises said nucleic acid, and a suitable promoter, such as SV40 promoter, is operably linked to the said nucleic acid (page 17, [0189]). Furthermore, Paszty teaches a host cell containing said vector, wherein the host cell can be a bacterial cell such as E.coli, a yeast cell such as S. cerevisiae, an insect cell such as Sf-9, and a mammalian cell such as HEK-293 (page 18, [0197] – [0200]). Thus, the reference anticipates claims 1-5, 7-22, 67 and 68. Furthermore, Paszty teaches mRNA expression of LGR8 (Example 2), and therefore, the reference also anticipates claim 6.

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With respect to claims 25 and 26, although Paszty does not specifically mention a composition comprising said nucleic acid or vector and a carrier or diluent, however, it is well known in the art that a purified nucleic acid is usually used in combination with other agent(s), such as dissolving solutions, rather than used as its crystal form alone. Given the fact that Paszty uses the nucleic acid for the recombinant production of the polypeptide, said nucleic acid would be necessarily dissolved in buffer, water or medium for transforming or transfecting host cells. Dissolving solutions, such as water and buffers, meet the limitation of being "an acceptable carrier". Therefore, the reference anticipates the claims 25 and 26.

Furthermore, Paszty teaches a recombinant method of producing said polypeptide, including recovering the polypeptide from the lysate of the host cell, or the cell culture medium (page 18, [0206], and page 19, [0207]), and therefore, anticipates claims 27-29.

With respect to claims 69-71, the polynucleotide of claim 69, as written in the claim, is not necessarily different from that encoding nGPCR-1079 even though it is from a human with a mental disorder, as not all of mental disorders are caused by the change of nGPCR-1079. Therefore, the reference also anticipates claims 69-71.

Claims 1-9, 13, 16, 20-22, 25, 26, and 69-71 are rejected under 35 U.S.C. 102(a) as being anticipated by Chen et al., WO 01/36471 (25 May 2001, provided by applicants).

Chen discloses a nucleic acid, SEQ ID NO:17, which comprises the sequence of SEQ ID NO:1 of the present invention with 100% sequence identity (see appended computer printout of sequence search result), and encodes a human GPCR designated hRUP16, and having an amino acid sequence of SEQ ID NO:18. Chen's hRUP16 of SEQ ID NO:18 comprises the amino acid sequence of SEQ ID NO:2 of the present invention with 100% sequence identity (see appended computer printout of sequence search result). Additionally, Chen teaches a vector comprising said nucleic acid, a host cell containing the vector (claims 35 and 36), such as prokaryotic and eukaryotic host cells (page 9, lines 3-10), and recombinant expression of the polypeptide in yeast cells, and mammalian cells such as 293 cell (Example 3). As such, the reference anticipates claims 1-5, 7-9, 13, 16, 20-22. With respect to claim 6, as Chen's nucleic acid is expressed in a host cell, mRNA would be produced during the expression process, and therefore, the reference also anticipates claim 6.

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With respect to claims 25 and 26, although Chen does not specifically mention a composition comprising said nucleic acid or vector and a carrier or diluent, the reference anticipates the claims for the same reasons above.

Further, the reference anticipates claims 69-71 for the same reasons above.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-12, 14, 15, 17-19, 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al., WO 01/36471 (25 May 2001), as applied to claims 1-9, 13, 16, 20-22, 25, 26, and 69-71 above, and further in view of Glucksmann et al., US 5,945,307.

The teachings of Chen are reviewed above. Chen does not specify a viral vector (as claims 10 and 11), a promoter such as SV40 (as claim 12), a host cells such as E.coli, yeast *S. cerevisiae* or insect cell *S. frugiperda* (as claims 14, 15 and 17-19), or a method of producing the polypeptide by recovering said polypeptide from the host cell or the culture medium (claims 27-29).

Glucksmann discloses a nucleic acid encoding a human GPCR (abstract). Additionally, Glucksmann teaches an viral vector such as baculovirus expression vector (column 18, lines 61-62); a mammalian expression vector with viral regulatory element such as SV40 promoter; that the GPCR can be expressed in bacterial cells such as E.coli, insect cells such as Sf9, yeast cells such as *S. cerevisiae* (column 17, lines 55-62, and 66-67; and column 18, lines 54-66), and a recombinant method for producing the polypeptide from the medium or the host cell (column 20, lines 43-51). Glucksmann's teachings of expression vectors, host cells and the recombinant method listed above are well established and known in the art as multiple references are cited after each teaching.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to express the GPCR using the nucleic acid taught by Chen and the

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expression vector, the host cell and the recombinant method as mentioned by Glucksmann. The person of ordinary skill in the art would have been motivated to do so because the general knowledge of recombinant expression of proteins are well known and widely practiced, and reasonably would have expected success because Glucksmann has demonstrated the successful expression of a human GPCR.

Conclusion:

No claim is allowed.

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Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



LORRAINE SPECTOR
PRIMARY EXAMINER

Dong Jiang, Ph.D.
Patent Examiner
AU1646
7/8/03